

### REMARKS

Favorable reconsideration of this application, as presently amended and in light of the following discussion, is respectfully requested.

Claims 1, 4-7, 10, 11, 14-17, 20, 21, 24-27, and 30 are currently pending. Claims 1, 4-7, 11, 14, 15, 21, and 24-27 have been amended by the present amendment. The changes to the claims are supported by the originally filed specification and do not add new matter.

In the outstanding Office Action, Claims 1 and 11 were rejected under 35 U.S.C. § 112, first paragraph; Claims 1, 4-7, 10, 11, 14-17, and 20 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter; and Claims 1, 4-7, 10, 11, 14-17, 20, 21, 24-27, and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,282,305 to Huo et al. (hereinafter “the ‘305 patent”) in view of U.S. Patent No. 5,671,294 to Rogers et al. (hereinafter “the ‘294 patent”).

Amended Claim 1 is directed to a method implemented by a computer programmed as an image processing device that analyzes a mammogram in digital form of a breast of a patient, comprising (1) extracting from a selected region of interest in the mammogram, plural surface area values or plural volume values calculated at corresponding plural scales associated with a texture of a parenchyma of the breast; (2) applying, by the image processing device, said plural surface area values or said plural volume values directly as inputs to at least one of a linear discriminant classifier and an artificial neural network classifier; and (3) generating a risk marker indicative of a breast disease risk for said patient based on an output of the at least one of a linear discriminant classifier and an artificial neural network classifier. Claim 1 has been amended for the purpose of clarification only and no new matter has been added.<sup>1</sup>

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<sup>1</sup> See, e.g., Figures 4 and 5 and the discussion related thereto in the specification.

Applicants respectfully submit that the rejection of Claim 1 under 35 U.S.C. § 112, first paragraph, is rendered moot by the present amendment to Claim 1, or is otherwise traversed. In this regard, Applicants note that Claim 1 recites the step of applying the plural surface area values or volume or the plural volume values directly as inputs to at least one of a linear discriminant classifier and an artificial neural network classifier. In particular, Applicants note that Figure 4 shows a graph of points representing different combinations of pixel size and surface area. In particular, the Y-axis represents surface area. Further, Figure 4 shows lines from the plotted surface area points to a linear discriminant analyzer (LDA). Further, Applicants note that page 19, lines 24-26 of the originally filed specification states that “[l]inear discriminant analysis (LDA) was applied on surface areas  $A(\epsilon)$  calculated at multiple pixel sizes  $\epsilon$ ”. Thus, Applicants respectfully submit that Figure 4 and page 19 of the originally filed specification clearly provide support for plural surface area values being applied directly as inputs to a linear discriminant classifier.

Similarly, Figure 5 illustrates volume values plotted against the corresponding pixel size at which the volume values were obtained, and shows that the volume value points are directly applied to the linear discriminant analyzer (LDA), as illustrated by the straight lines from the points to the LDA shown in Figure 5. Further, Applicants note that page 21, lines 1-7 state that, contrary to prior art systems, which must compute the slope of the points, which could be difficult since it could be multi-fractal in nature, the present method uses either linear discriminant analysis or an artificial neural network to analyze the points, rather than trying to determine the slope or the multiple slopes in the graph.

Accordingly, for the reasons stated above, Applicants respectfully submit that applying plural surface area values or plural volume values directly to a classifier is clearly not new matter and is clearly supported by Applicants’ specification. Accordingly,

Applicants respectfully request that the rejection of Claims 1 and 11 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Applicants respectfully submit that the rejections of the claims under 35 U.S.C. § 101 are rendered moot by the present amendment to Claim 1. Claim 1 has been amended to be directed to a method implemented by a computer programmed as an image processing device that analyzes a mammogram, and to clarify that the applying step is performed by the image processing device. Thus, Applicants respectfully submit that the method recited in Claim 1 is now tied to a particular apparatus, i.e., an image processing device. Thus, since Claim 1 is tied to a particular machine, Claim 1 satisfies the machine-or-transformation test set forth in *In re Bilski*. Further, Applicants note that Claim 1 transforms data related to a mammogram, which is data that corresponds to a physical object, to a different state or thing. Accordingly, based on the *In re Abele* case, which involved the transformation of X-ray data and was cited with approval in *In re Bilski*, Applicants respectfully submit that amended Claim 1 also satisfies the machine-or-transformation test because it satisfies the transformation branch of that test.

Further, Claim 11 has been amended to include a memory storing the mammogram in digital form. Accordingly, Applicants respectfully submit that Claim 11 is clearly not directed to software *per se*, since it includes a memory, which is a hardware device. Accordingly, for the reasons stated above, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. § 101 are rendered moot by the present amendment to the claims.

Regarding the rejection of Claim 1 under 35 U.S.C. § 103(a), the Office Action asserts that the '305 patent discloses everything in Claim 1 with the exception of "multiple scales,"<sup>2</sup> and relies on the '294 patent to remedy that deficiency.

The '305 patent is directed to a method for the computerized assessment of breast cancer risk, including the steps of obtaining a digital image of a breast of a person, determining values of parenchyma features of a breast region at a predetermined parenchyma location in the digital image, which includes determining the value of a skewness feature based on gray-level as to RAM analysis of pixels within the predetermined parenchymal location. Further, the '305 patent discloses that values of coarseness and contrast features, as well as a balance feature and a first moment of the power spectrum feature may be determined. Further, the '305 patent discloses that the method for computerized assessment of breast cancer risk includes the step of comparing the values of the determined features with a predetermined model associating values of the features with a respective risk estimate, and outputting a result of the comparing step as a risk classification index indicating likelihood of future onset of breast cancer.

However, as apparently admitted by the outstanding Office Action, the '305 patent fails to disclose extracting plural features at multiple scales from a mammogram. In particular, Applicants respectfully submit that the '305 patent fails to disclose extracting, from a selected region of interest in the mammogram, plural **surface areas** or plural **volumes** calculated at corresponding plural scales associated with a texture of a parenchyma of the breast, as recited in amended Claim 1. In this regard, Applicants note that the passages cited by the outstanding Office Action regarding the extracting step in columns 9 and 10 of the '305 patent do not mention fractal-based features, or in particular, **surface areas of volumes**. The '305 patent mentions fractal dimension only in passing with respect to various prior art

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<sup>2</sup> See page 9 of the outstanding Office Action.

studies.<sup>3</sup> In particular, Applicants note that the Office Action on page 2 cites to column 13, lines 36-39 in the '305 patent. However, that passage relates to 14 features that are extracted, none of which are volume values or surface area values at corresponding plural scales, as required by Claim 1. Applicants refer the Examiner to the 14 features described in columns 13-15 of the '305 patent.

Further, Applicants respectfully submit that the '305 patent fails to disclose the step of applying, by the image processing device, the plural surface area values or the plural volume values directly as inputs to at least one of a linear discriminant classifier and an artificial neural network classifier, as recited in amended Claim 1. In this regard, Applicants note that a computing a fractal dimension, for example, by finding the slope of a graph of the log of surface area to log of pixel size is not the same as applying plural surface area values or plural volume values directly as inputs to a linear discriminant classifier. As shown in the non-limiting example of Figure 4, fractal dimension can be computed by determining the slope of the points in a graph of the log of the surface area to the log of the pixel size. However, Applicants note that Claim 1 requires applying the plural surface area values or plural volume values, e.g., the data points in Figure 4, directly as inputs to a linear classifier or an artificial neural network.

The '294 patent is directed to a method for distinguishing and classifying textures of an image in a supervised feature generation system including the steps of obtaining a digitized image file; obtaining texture classification information representative of pixels within the image; computing local area averages for each scale and dependent upon intensity differences and a segmentation map; and computing power log features of the image. In particular, as noted by the outstanding Office Action, the fractal dimension of the image can be obtained using Richardson's law, which is equivalent to finding the slope of the curve in a

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<sup>3</sup> See, e.g., '305 patent, column 11, lines 33-36.

graph of the log of a major property  $M(\epsilon)$  versus the log of  $\epsilon$ . In particular, Applicants note that, as disclosed in column 8, the '298 patent discloses that such a regression on the log of an area curve versus the log of  $\epsilon$  is used to find the slope for each pixel, wherein the '294 patent computes such a slope for each area centered around a particular pixel.<sup>4</sup> Further, the '294 patent discloses that the slope as well as the Y-intercept and the F-test of the regression provide "power log features" for the pixel, which can be used for classification.

However, Applicants respectfully submit that the '294 patent fails to disclose the step of applying plural surface area values or plural volume values **directly** as inputs to at least one of the linear discriminant classifier and an artificial neural network classifier, as recited in amended Claim 1. Rather, as discussed above, the '294 patent clearly discloses computing the fractal dimension by finding the slope of the log of the area versus the log of  $\epsilon$  curve for each region centered at a particular pixel. The '294 patent does not disclose applying plural surface area values or plural volume values directly as inputs to a linear discriminant classifier or an artificial neural network, as required by Claim 1.

Thus, no matter how the teachings of the '305 and '294 patents are combined, the combination does not teach or suggest the step of applying, by the imaging processing device, the plural surface area values or the plural volume values directly as inputs to at least one of a linear discriminant classifier and an artificial neural network classifier, as recited in amended Claim 1. As discussed above, the '305 patent fails to disclose the volume values or the surface area values recited in Claim 1. Further, the '294 patent merely describes the conventional computation of the fractal dimension based on the slope of points in a surface area to scale graph, but does not teach or suggest the inventive concept of applying surface area values or volume values directly to a classifier. Thus, it is clear that, no matter how the teachings of the '294 and '305 patents are combined, the combination does not teach or

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<sup>4</sup> See '294 patent, column 8, lines 9-15.

suggest applying plural surface area values or plural volume values directly to a classifier, as required by Claim 1. Accordingly, for the reasons stated above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and that the rejection of Claim 1 (and all associated dependent claims) should be withdrawn.

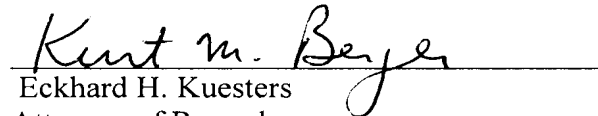
Independent Claims 11 and 21 are directed to a system for computerized analysis of a mammogram and a computer readable medium storing instructions for execution on a computer system, respectively. Further, Applicants note that Claims 11 and 21 recite functional limitations analogous to those recited in Claim 1 and have been amended in a manner analogous to the amendment to Claim 1. In particular, Applicants note that Claims 11 and 21 also recite applying plural surface area values or plural volume values directly as inputs to at least one of linear discriminant classifier and an artificial neural network classifier. As discussed above, this limitation is not disclosed by any proper combination of the cited references. Accordingly, Applicants respectfully submit that the rejections of Claim 11 and 21 (and all associated dependent claims) are rendered moot by the present amendment to those claims.

Thus, it is respectfully submitted that independent Claims 1, 11, and 21 (and all associated dependent claims) patentably define over any proper combination of the '305 and '294 patents.

Consequently, in view of the present amendment and in light of the above discussion, the outstanding grounds for rejection are believed to have been overcome. The application as amended herewith is believed to be in condition for formal allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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A handwritten signature in cursive script, reading "Kurt M. Berger", is written over a horizontal line.

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